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P#14

DOCKET NO.: TJU-2414/WAL01-NHP407

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Scott A. Waldman, et al.

Confirmation No.: 2093

Serial No.: 09/819,254

Group Art Unit: 1642

Filing Date: March 27, 2001

Examiner: Misook Yu

**For: COMPOSITIONS AND METHODS FOR IDENTIFYING AND TARGETING
CANCER CELLS OF ALIMENTARY CANAL ORIGIN**

EXPRESS MAIL LABEL NO: EV 058085883 US

DATE OF DEPOSIT: 4/4/03

EV058085883US

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☐ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or

before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;
or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☒ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith

EXCEPT THAT:

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- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. , filed .
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

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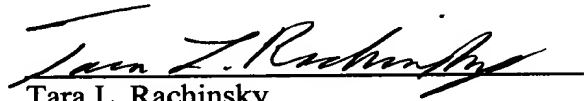
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Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Enclosed is a copy of the EPO Supplementary Partial European Search Report dated February 28, 2003 (no. 12 on the PTO-1449), which indicates the references considered to be relevant.

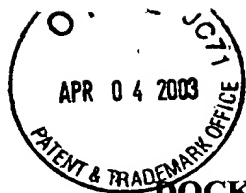
There are no listed references which are not in the English language.

Date: *April 4, 2003*


Tara L. Rachinsky
Registration No. 47,875

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

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Washington DC 20231

Dear Sir:

CERTIFICATION UNDER 37 CFR § 1.97(e)

In accordance with 37 CFR § 1.97(e), certification is hereby made that:

- ☒ Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the

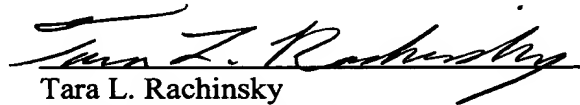
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information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

Date: *April 4, 2003*


Tara L. Rachinsky
Registration No. 47,875

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. TJU-2414/ WAL01-NHP407	Serial No. 09/819,254
	APR 11 2003	
	Applicant Scott A. Waldman, et al.	
	Filing Date March 27, 2001	Group 1642

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	12	Copy of the EPO Supplementary Partial European Search Report dated February 28, 2003 (EP 01 92 2738)
	13	Bostick, P.J., "Limitations of specific reverse-transcriptase polymerase chain reaction markers in the detection of metastases in the lymph nodes and blood of breast cancer patients," XP-000929382, <i>J. Clinical Oncology</i> , August 1998, 16(8), 2632-2640
	14	Bustin, S.A., et al., "Detection of cytokeratins 19/20 and guanylyl cyclase C in peripheral blood of colorectal cancer patients," <i>British J. Cancer</i> , XP-000949369, 1999, 79(11/12), 1813-1820
	15	Carrithers, S.L., et al., "Guanylyl cyclase C is a selective marker for metastatic colorectal tumors in human extraintestinal tissues," <i>Proc. Natl. Acad. Sci. USA</i> , XP-002232686, December 1996, 93, 14827-14832
	16	Chelly, J., et al., "Illegitimate transcription: transcription of any gene in any cell type," <i>Proc. Natl. Acad. Sci. USA</i> , XP-001018967, April 1989, 86, 2617-2621
	17	Champelovier, P., et al., "CK20 gene expression: technical limits for the detection of circulating tumor cells," <i>Anticancer Research</i> , XP-000949390, 1999, 19, 2073-2078
	18	Cooper, D.N., et al., "Ectopic (illegitimate) transcription; new possibilities for the analysis and diagnosis of human genetic disease," <i>Ann. Med.</i> , XP009006533, 1999, 26, 9-14
	19	Eschwège, P., "Haematogenous dissemination of prostatic epithelial cells during radical prostatectomy," <i>Lancet</i> , XP-001145689, December 9, 1995, 346, 1528-1530
	20	Gala, J-L., et al., "Expression of prostate-specific antigen and prostate-specific membrane antigen transcripts in blood cells: implications for the detection of hematogenous prostate cells and standardization," <i>Clinical Chemistry</i> , XP-002232688, 1998, 44(3), 472-481
	21	Gala, J-L., et al., "Sensitivity or specificity of reverse transcriptase-polymerase chain reaction assays: the real challenge for molecular staging of prostatic carcinomas," Letter to the Editor, <i>Int. J. Cancer</i> , XP-002232687, 1998, 77, 161-163
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		Applicant Scott A. Waldman, et al.	
		Filing Date March 27, 2001	Group 1642
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	22	Grasso, Y.Z., et al., "Combined nested RT-PCR assay for prostate-specific antigen and prostate-specific membrane antigen in prostate cancer patients: correlation with pathological stage," <i>Cancer Research</i> , XP-001145491, April 1, 1998, 58, 1456-1459	
	23	Israeli, R.S., et al., "Sensitive nested reverse transcription polymerase chain reaction detection of circulating prostatic tumor cells: comparison of prostate-specific membrane antigen and prostate-specific antigen-based assays," <i>Cancer Research</i> , XP-000931336, December 15, 1994, 54, 6306-6410	
	24	Miltyi S., et al., "High gradient magnetic cell separation with MACS," <i>Cytometry</i> , XP-000999711, 1990, 11, 231-238	
	25	Neumaier, M., et al., "Diagnosis of micrometastases by the amplification of tissue-specific genes," <i>Gene</i> , 1995, 159, 43-47	
	26	Smith, M.R., "Prostatic-specific antigen messenger RNA is expressed in non-prostate cells: implications for detection of micrometastases," <i>Cancer Research</i> , XP002910142, June 15, 1995, 55, 2640-2644	
	27	Waldman, S.Ca., et al., "Heterogeneity of guanylyl cyclase C expressed by human colorectal cancer cell lines <i>in vitro</i> ," <i>Cancer Epidemiology, Biomarkers & Prevention</i> , XP009006094, June 1998, 7, 505-514	
	28	Wong, I.H.N., et al., "Quantitative analysis of circulating tumour cells in breast cancer patients using reverse transcriptase polymerase chain reaction," <i>European J. of Cancer</i> , XP004384226, September 1999, page S90 (abstract)	
	29	Zippelius, A., et al., "Limitations of reverse-transcriptase polymerase chain reaction analyses for detection of micrometastatic epithelial cancer cells in bone marrow," <i>J. Clinical Oncology</i> , XP-002079149, July 1997, 15(7), 2701-2708	
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Sheet 3 of 3

Form PTO-1449 ModifiedList of Patent and Publications
Cited by Applicant
(Use several sheets if necessary)U.S. Department of Commerce
Patent and Trademark OfficeDocket No.
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09/819,254Applicant
Scott A. Waldman, et al.Filing Date
March 27, 2001Group
1642**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass

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